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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,061	06/26/2001	Nicholas R. Bachur JR.	P-5026	1747

63863 7590 08/09/2007

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/892,061	BACHUR ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007 and 08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65,67,68,79-89,91,92,96-99 and 113-145* is/are pending in the application.

4a) Of the above claim(s) *65,67,68,79-89,91,92,96-99 and 123-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *113-115 and 119-122* is/are rejected.

7)☒ Claim(s) *116-118* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/16/2007 has been entered.

Election/Restrictions

2. Applicant's election of Group II, Claims 113-122, in the reply filed on 5/8/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 65, 67, 68, 79-89, 91, 92, 96-99 and 123-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/8/2007.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 119 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 119 it is not clear if the recited housing is a further limitation of the module recited in claim 113 or an additional structure in the system. Clarification and/or correction is requested.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 113-115, 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector. With respect to the claimed plurality of containers and modules with a plurality of openings, the reference of Sussman et al. discloses the use of a module (track) with openings for holding a plurality of containers (See column 3, lines 49-61).

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas is exists in the container, instant claim 113 requires that a

laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of

providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 113 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which oxygen, ammonia, hydrogen sulfide, methane or sulfur dioxide absorbs radiation.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Wong discloses that it is known in the art to employ diode lasers to detect oxygen within a gas sample (See column 5, lines 12-59).

The reference of Allen discloses that it is known in the art to employ diode lasers to detect gases including ammonia, methane, hydrogen sulfide and sulfur dioxide within a gas sample (See page 14, first full paragraph and page 33, lines 8-11).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example oxygen, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of a diode laser system as disclosed by Wong or Allen would provide art recognized diode lasers capable of

detecting the gases suggested by Ahnell while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

Finally claim 113 differs by requiring that the device includes a plurality of lasers and detectors wherein each laser emits radiation at a substantially single wavelength that is different from the other lasers.

As discussed above, the references of Sussman and Ahnell suggest that gases other than carbon dioxide can be detected within the culture vessels. In the absence of a showing of criticality and/or unexpected results, when detecting for a plurality of different gas components within the culture vessel as suggested by the references of Sussman and Ahnell, it would have been obvious to one of ordinary skill in the art to provide a plurality of laser/detector pairs that correspond to the specific gas components to be detected for the known and expected result of eliminating the need to tune a single diode laser through a plurality wavelengths a facilitating the detection of the desired gas components.

Note the system as discussed above would be capable of determining the presence and/or concentration of the gas components in the container

With respect to claim 114, the laser suggested by the prior art would be a monomodal laser.

With respect to claim 115, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 121, the reference of Sussman optically analyzes the neck portion of the sample vial.

With respect to claim 122, if the reference of Sussman does not inherently disclose a bracket for holding the light emitter and detector while the containers pass by, it would have been well within the purview of one having ordinary skill in the art to provide the device with a bracket for holding the sensing components of the device while the container pass by the detection system.

10. Claims 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al., Wong and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation

environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

Allowable Subject Matter

11. Claims 116-118 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter:

While the prior art rejections of record suggest a system that includes a bracket or housing for holding a plurality of lasers and detectors for movement relative to a plurality of culture containers, the prior art of record fails to teach or fairly suggest the features of claims 116-118 including a housing for holding the plurality of laser and detectors wherein the housing is movable between a plurality of container and wherein the lasers and detectors are also movable within the movable housing.

Response to Amendment

13. The declarations filed on 4/26/06 and 1/16/07 under 37 CFR 1.131 has been considered but is ineffective to overcome the Veale (US 6,639,678) reference.

The declaration has been determined to be ineffective for the following reasons:

The evidence of conception and reduction to practice is not commensurate in scope with the instant claims.

Note independent claim 113 requires a plurality of lasers that emit radiation at a substantially single wavelength wherein the single wavelength is one at which a gas selected from O_2, CO_2, NH_3, H_2S or CH_4 absorbs radiation and a signal analyzer that analyzes the detected radiation for pressure, oxygen presence and/or concentration of the gas in the container. The evidence submitted is silent with respect to the use of a plurality of laser and detectors and/or any of the listed gases other than carbon dioxide recited in claim 113.

Even if applicant's 37 CFR 1.131 affidavit is not fully commensurate with the rejected claim, the applicant can still overcome the rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art. However, the affidavit or declaration showing must still establish possession of the invention (i.e., the basic inventive concept) and not just of what one reference (in a combination of applied references) happens to show, if that reference does not itself teach the basic inventive concept. In re Spiller, 500 F.2d 1170, 182 USPQ 614 (CCPA 1974) (See MPEP 715.02).

Response to Arguments

14. With respect to the combination of the references of Sussman et al. with Wrobel et al., Noller or Veale, Applicants argue that the rejection is improper for the following reasons:

The claims are commensurate in scope with the declarations filed under 37 CFR 1.131 dated 4/26/06 and 1/16/07 because the declarations and claims are limited to a wavelength of 2.004 microns when detecting carbon dioxide (See pages 13-14 of Applicants' response filed 1/16/2007).

In response, claim 113 is not limited to carbon dioxide as the detected gas. The claim language encompasses a device that can detect gases other than carbon dioxide and thus is not considered commensurate in scope with the declaration. Additionally, claim 113 includes a plurality of laser and detectors. Again, this is not commensurate with the declarations filed. As a result, the reference of Veale is still applicable as prior art against the claims.

The reference of Sussman et al. does not disclose the claimed 2.004 micron wavelength required of the instant claims (See pages 15-16 of Applicants' response filed 1/16/07).

In response, instant claim 113 is not limited to a device that requires this single wavelength. Claim 113 can include a device that only detects oxygen and ammonia and as a result, the prior art does not have to disclose the 2.004 micron wavelength to meet the instant claim limitations.

The reference of Sussman et al. teaches the use of FR-IR technique which teaches away from single wavelength laser source.

In response, for the reasons set forth in the prior art rejections of record, the prior art suggests the advantages of using a diode laser detection system of FR-IR spectroscopy.

The reference of Sussman et al. does not identify the other metabolic gases formed that can be detected (See page 17 of Applicants' response filed 1/16/2007).

In response, the reference of Ahnell et al. was cited to evidence what metabolic gases are known to those of ordinary skill in the art.

The reference of Sussman et al. fails to identify specific materials or wavelengths of transmittance associated with the detection of other metabolic gases (See page 17 of Applicants' response filed 1/16/2007).

In response, the secondary references of record teach and/or suggest the types of gases that are capable of being detected in a container system using laser diodes.

The references of Wrobel et al. and Nix do not disclose the specific wavelengths required of the instant claims (See pages 18-19 of Applicants' response filed 1/16/2007).

In response, while claim 118 recites the use of 2.004 micron wavelength to detect carbon dioxide, the claim is not limited to this specific claim limitation.

The reference of Noller is improper to use in the rejections because it is drawn to the use of liquid detection and not gas detection (See pages 18-19 of Applicants' response filed 1/16/2007).

The reference of Noller was cited as a teaching reference as to the advantages of using a laser diode over other spectrophotometry methods. One of ordinary skill in the art would clearly recognize that it is notoriously well known in the art to employ spectrophotometry in the analysis of both liquids and gases. As a result, the equipment advantages associated with the use of laser diodes would be beneficial in both liquid and/or gas analysis.

The reference of Ahnell et al. is drawn to mass spectrometry and does not teach any of the details of the instantly claimed invention (See page 20 of Applicants' response filed 1/16/2007).

In response, the reference of Ahnell et al. was merely relied upon as evidencing the specific types of metabolic gases that are present within a culture container similar to that of the reference of Sussman et al.

The reference of Wong et al. does not disclose the use of a single wavelength (See pages 20-21 of Applicants' response filed 1/16/2007).

In response, the reference of Wong et al. was cited as evidence that it is well known in the art to employ laser diodes when detecting oxygen in a gas. In view of the prior art of record, one of ordinary skill in the art would be capable of determining whether to use a single wavelength or scan through a plurality of wavelengths. Regardless, the disclosed laser diodes are capable of being tuned to a single wavelength as recited in the claims.

The reference of Allen et al. does not disclose the use of a single wavelength detection required of the instant claims (See pages 23-24 of Applicants' response filed 1/16/2007).

In response, the reference of Allen et al. was cited as evidence that it is well known in the art to employ laser diodes when detecting different gas components in a gas. In view of the prior art of record, one of ordinary skill in the art would be capable of determining whether to use a single wavelength or scan through a plurality of wavelengths. Regardless, the disclosed laser diodes are capable of being tuned to a single wavelength as recited in the claims.

The rest of Applicants' comments (See pages 21-24 of Applicants' response filed 1/16/2007) stress that the additional references of record fail to make up for the deficiencies related to the reference of Sussman et al.

In response, the additional references were merely relied upon to address the additional claim limitations recited in the dependent claims.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1744

WHB